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To Evaluate Enteric Performance of Instacoat EEN-SF at Low Weight Gain

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PURPOSE

An enteric coating is a barrier that controls the release of oral medication in the digestive system where it is absorbed. The marketed enteric coating formulations are applied at 8-12% weight gain for enteric protection. Thus processing time as well as energy consumption are quite high with consequent increased costs. Ideal Cures has taken the challenge by developing an acrylic based enteric coating formulation INSTACOAT EEN-SF. It is a ready mix enteric coating formulation for solid oral dosage forms, providing enteric protection at lower weight gain thus reducing processing time, energy consumption and as a result overall cost. The present study evaluates the coating efficiency and enteric performance of Instacoat EEN-SF at 5% weight gain.

Figure 1. Perforated Coating Pan

Figure 2. Spraying Gun

METHOD

MATERIALS AND METHODS

The Instacoat EEN-SF formulation was reconstituted at 13% w/w solids in a hydroalcoholic system (IPA:Water 85:15). The coating suspension was evaluated for appearance, viscosity and pH. The suspension was then filtered through a 100# nylon cloth prior to coating process. Coating trials were carried out on seal coated circular biconvex multienzyme tablets in a perforated pan (48") to 5% weight gain.

Table 1. Coating Material Details

Coating Formulation Details	
Product Name	INSTACOAT EEN-SF
Colour	White

COATING PROCESS

A) Seal Coating

Round biconvex multienzyme core tablets were used as the substrate. Core tablets were seal coated with Instacoat IC-MS-2398 (Organic System) to a 2% weight gain.

Table 2. Core Tablets and Seal Coating Details

Seal coating material	Instacoat IC-MS 2398
Reconstitution Level (% w/w)	5
Solvent used	IPA/ MDC (35:65)
Active ingredients	Lipase, Pancreatin, Protease

Table 3. Coating Parameters for Seal Coating of Tablets

Pan Speed (RPM)	Pump Speed (RPM)	Inlet Air Temp. (°C)	Bed Temperature (°C)	Atomizing Air Pressure (Kg/cm²)
2-5	6	65-67	36-38	1.5-2.0

B) Enteric Coating

- The Instacoat EEN-SF formulation was reconstituted at 13% w/w solids in a hydroalcoholic system (IPA:Water 85:15). Seal coated circular biconvex multienzymes tablets were us
- The tablets were coated with Instacoat EEN-SF suspension to a 5% weight gain. Coated tablets were evaluated for enteric performance , appearance and coating defects. The disintegration tests of tablets were performed to check the enteric efficiency of Instacoat EEN-SF at 5% weight gain. The trials were performed on three batches to verify the reproducibility of the results.

Table 4. Seal Coated Tablet Details

Active ingredients	Lipase, Pancreatin, Protease
Weight Gain (%)	2-2.5
Avg. weight of 20 tablets (g)	7.36
Disintegration time of seal coated tablets (Minutes.)	17-18

Table 5. Coating Parameters for Enteric Coating of Tablets

Batch	1	2	3
Batch Size (Kg.)	145	145	145
Product Bed Temperature (ºC)	31-34	31-33	31-32
Differential Pressure Gauge (mm water)	8	8	8
Atomizing Air Pressure (kg/cm2)	2.2-2.4	2.2-2.5	2.2-2.4
Pan Speed (rpm)	2.5-8	2.5-7	3-7
Spray Rate (g/min)	90-200	150-240	150-190
Gun to Bed Distance (cm)	18-19	18-19	17-19

RESULTS

- The coating trials of Instacoat EEN-SF were successfully executed for 3 batches of 145 Kg each using the perforated pan without any coating issues.
- Trial outcomes were found acceptable.

Table 6. Observations

Parameter	Batch 1	Batch 2	Batch 3
(A)Coating suspension characteristics			
Sprayablity	White ,smooth and easily sprayable coating suspension		
pH	5-6		
Viscosity (cP)	33.6	34.1	33.2
Filtration Through 100# mesh	No retention		
(B) Process feasibility			
Gun Choking	No gun blocking observed		
(C) Coated Tablets Evaluation*			
Appearance	Smooth and Glossy		
Coating Defects	No defects observed		

* 100 tablets were observed for appearance and Coating defects.

Table 7. Disintegration Test

Medium	Batch 1	Batch 2	Batch 3
0.1 HCl	Tablets were Intact after 2 hours.		
Phosphate Buffer pH 6.8	Tablets disintegrated in 22.5 mins.	Tablets disintegrated in 25.1 mins.	Tablets disintegrated in 23.5 mins.

Fig.1 Coated Tablets

CONCLUSION

Instacoat EEN SF a fully formulated, water-dispersible, acrylic based film coating system provided the desired enteric protection at 5 % coating weight gain.

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